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EXHIBIT 2
Summary of Safety and Effectiveness

日本精密測器株式会社
NIHON SEIMITU SOKKI CO.,LTD.

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Contact: Y. Shibata, Chief Engineer

1. **Identification of the device**
Proprietary-Trade Name: Model WT-20 Wrist Blood Pressure Monitor & Fat Meter
Classification Names: DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE, 74 MNW ANALYZER, BODY COMPOSITION
Common/Usual Name: Wrist blood pressure monitor/Body fat meter

2. **Equivalent legally marketed devices**
This product is similar in function and design to the Omron HBF-306 Body Fat Analyzer K011652, and has the blood pressures and pulse rate measurement of Nihon Seimitsu Sokki Co., Ltd. (Nissei) WS-500 Digital Wrist Blood Pressure Monitor K003444.

3. **Indications for Use (intended use)**
Combination unit for measuring systolic and diastolic blood pressures and pulse rates in adult patients with arm circumference between 4.9" to 8" inches as well as body composition, i.e. estimation of body fat, a noninvasive bioimpedance analyzer for use in estimating the human's body fat volume (mass) and percentage by weight. Age range 10-80 years normal subjects, 18-80 years for athletic subjects.

4. **Description of the Device**
The Model WT-20 Wrist Blood Pressure Monitor & Fat Meter combines the familiar wrist blood pressure monitor found over the counter in drug stores with a body composition/body fat meter.

5. **Safety and Effectiveness, comparison to predicate device**
The results of bench and user testing indicate that the new device is as safe and effective as the predicate devices.

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6. Comparison matrix – new vs. Predicate device

Designation	OMRON Body Fat Analyzer HBF-306 K011652	Nissei WT-20
Operating Principle	Bioelectrical Impedance Analysis (BIA)	SAME (Also measures blood pressure)
Display	Body fat percentage (4.0 to 50.0%) BMI (7.0 to 90.0) BMI classification (4 levels)	5.0 to 50.0 % (body fat) 5 to100 (BMI) BMI classification (4 levels)
Measurement Time	7 Seconds	5 to 10 seconds
Set ranges	Height: 3'4" to 6'6" (101cm. to 198cm.) Weight: 23lbs. to 440 1/2 lbs (10kg.to220kg.) Age: NORMAL; 10 to 80 years old ATHLETE; 18 to 60 years old Gender: Male / Female	M1, M2, M3 and M4 or neutral (registration number) 22 to 440pounds(weight) 36 to 79inches (height) 10 to 80 (age) Male or female (sex)
Power supply	2 AAA batteries (R03)	SAME (Alkaline recommended)
External dimensions	197(L) × 128(H) × 49mm(W)	93 (W) × 75 (H) × 37.5 (D) mm
Memory	9 personal profile memories	4 sets of weight, height, age, sex and 10 measurement results of blood pressure and body fat
Weight	Approx.230 g (not including batteries)	Approx, 113g (without batteries), 150 g with batteries
Accessories	2 AAA batteries for monitor use Instruction manual Body Logic Fitness and Nutrition Guide	2 AAA batteries for monitor use Instruction manual

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of Nissei that the "WT-20" Wrist Blood Pressure Monitor and Fat Meter is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nihon Seimitsu Sokki Co., Ltd.
c/o Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K031582
Trade Name: Model WT-20 Wrist Blood Pressure Monitor & Fat Meter
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph.
Regulatory Class: Class II (two)
Product Code: MNW
Dated: May 7, 2003
Received: May 21, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9. Indications for Use

510(k) Number K031582

Device Name: Nissei Model WT-20 Wrist Blood Pressure Monitor & Fat Meter

Indications for Use: Combination unit for measuring systolic and diastolic blood pressures and pulse rates in adult patients with arm circumference between 4.9" to 8" inches as well as body composition, i.e. estimation of body fat, a noninvasive bioimpedance analyzer for use in estimating the human's body fat volume (mass) and percentage by weight. Age range 10-80 years normal subjects, 18-80 years for athletic subjects.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use____X____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031582